

REMARKS

Claims 1-14 are under examination, and Claims 15-43 have been withdrawn as non-elected subject matter.

1. Rejection Under 35 U.S.C. §112, Second Paragraph.

The Examiner rejected Claim 9 under 35 U.S.C. §112, second paragraph, as being indefinite, stating that use of the word "and" in line 3 makes the claim unclear. Applicants have amended Claim 9 to include proper wording for a Markush group so that the claim now states that "the polymer is selected from the group consisting of polylactic acid, polyglycolic acid, polycaprolactone, poly  $\alpha$ -hydroxy esters, polyphosphazenes, polyanhydrides, and polypropylene fumarate."

2. Rejection Under 35 U.S.C. §102

The Examiner rejected Claims 1-3 and 6 under 35 U.S.C. §102(b) as being anticipated by Radin et al. (WO 97/41,842). The Examiner states that Radin et al. "teaches compositions comprising hollow calcium phosphate containing glass shells . . . that are combined with biologically active molecules such as BMP or collagen," and that "[t]he particles vary in size from about 50 mcm - 5 mm."

Claim 1 has been amended to recite that the composition comprises hollow sintered calcium-containing microstructures and a bone mixture. Support for use of the term "sintered" can be found in the specification, for example, on p.15, ll. 23-25. The composition disclosed in Radin et al. includes hollow calcium phosphate shells that are formed *in vitro* by a process in which silica-based, calcium and phosphate-containing glasses are transformed into hollow shells having an outer, nanoporous, carbonated amorphous or crystalline CaP-rich layer. These glass-based particles are not sintered materials and therefore, the disclosure of Radin et al. does not anticipate Claims 1-3 and 6.

3. Rejection of Claims Under 35 U.S.C. §103(a).

A. Rejection of Claims 1-6 over Radin et al. in view of U.S. Patent No. 5,273,964.

The Examiner rejected Claims 1-6 under 35 U.S.C. §103(a) as being unpatentable over Radin et al. in view of U.S. Patent No. 5,273,964 to Lemons. In this combination, the Examiner cited Radin et al. as teaching compositions comprising hollow CaP containing glass shells that are combined with biologically active molecules such as BMP or collagen. The Examiner states that Radin et al. does not teach the claimed amounts of a bone mixture. The Examiner, however, takes the position that the claimed amounts of bone mixture (Claims 4 and 5) would have been arrived at by one of ordinary skill in the art by routine experimentation. The Examiner further states that although Radin et al. do not teach the microstructures comprising each of the claimed calcium materials (Claim 6) that it would have been obvious to one with ordinary skill in the art to rely on the teaching of U.S. 5,273,964 which discloses particles made from tricalcium phosphate and hydroxylapatite.

To establish a *prima facie* case of obviousness under 35 U.S.C. §103(a), the Examiner must show that (1) the references teach all the elements of the claimed invention, (2) the references contain some teaching, suggestion or motivation to combine the references, and (3) the references suggest a reasonable expectation of success. In this rejection, the combination of references fails to teach all of the elements of the claimed invention, namely, a hollow sintered calcium-containing microstructure.

Neither Radin et al. nor U.S. 5,273,964 disclose or suggest, alone or in combination, the present invention. Specifically, as noted above in the discussion regarding the rejection under 35 U.S.C. §102, Radin et al. do not disclose a hollow sintered calcium-containing microstructure. Further, the citation of U.S. 5,273,964 does not make up this deficiency. While this patent discloses a composition for treatment of bone lesions that includes both particulate hydroxylapatite and particulate tricalcium phosphate ceramic, U.S. 5,273,964 does not disclose hollow microstructures. While U.S. 5,273,964 does refer to "microporous" materials, such materials are not hollow. A hollow structure, on the other hand, includes a significant void in its interior that is defined by an outer coating of material.

B. Rejection of Claims 1-3 and 7-14 over Radin et al. in view of U.S. Patent No. 5,085,861 to Gerhart et al.

The Examiner rejected Claims 1-3 and 7-14 under 35 U.S.C. §103(a) as being unpatentable over Radin et al. in view of U.S. Patent No. 5,085,861 to Gerhart et al. In this combination, the Examiner cited Radin et al. as teaching compositions comprising hollow calcium phosphate containing glass shells that are combined with biologically active molecules such as BMP or collagen. The Examiner states that Radin et al. do not teach that the composition further comprises a bonding agent that is one of the claimed polymers or calcium containing cements, or wherein the cement is present in the claimed amounts. The Examiner, however, takes the position that U.S. 5,085,861 teaches that cements, such as polyesters, polyanhydrides, and/or polypropylene fumarate, are well known and commonly used in compositions containing calcium phosphate or calcium sulfate particles for repairing and fixing bone defects. The Examiner takes the further position that while the references do not disclose the claimed amounts of cement (Claims 11 and 12), they would have been arrived at by one of ordinary skill in the art by routine experimentation.

To establish a *prima facie* case of obviousness under 35 U.S.C. §103(a), the Examiner must show that (1) the references teach all the elements of the claimed invention, (2) the references contain some teaching, suggestion or motivation to combine the references, and (3) the references suggest a reasonable expectation of success. In this rejection, the combination of references fails to teach all of the elements of the claimed invention, namely, a hollow sintered calcium-containing microstructure.

Neither Radin et al. nor U.S. 5,085,861 disclose or suggest, alone or in combination, the present invention. Specifically, as noted above in the discussion regarding the rejection under 35 U.S.C. §102, Radin et al. do not disclose a hollow sintered calcium-containing microstructure. Further, the citation of U.S. 5,085,861 does not make up this deficiency. While this patent discloses a biodegradable cement composition adapted for use in the surgical repair of living bone and for the controlled-release delivery of pharmaceutical agents, U.S. 5,085,861 does not disclose hollow microstructures. While U.S. 5,273,964 does refer to “sintered calcium phosphate ceramics and more porous and resorbable calcium salts,” such materials are not hollow. A hollow structure, for example, is one that includes a significant void in its interior

Application No. 10/030,578

with a relatively thin outer coating of material. That material can either be porous or dense, but to be hollow, the structure must include a void on its interior.

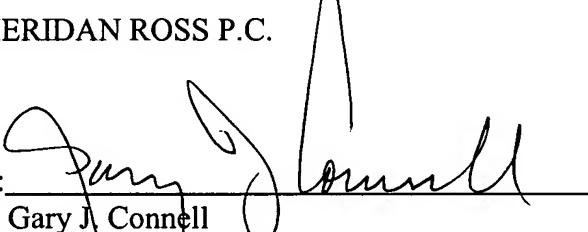
4. Obviousness-Type Double Patenting Rejections

The Examiner rejected Claims 1-6 under the judicially created doctrine of obviousness-double patenting as being unpatentable of Claims 1-3, 5, and 7-8 of U.S. Patent No. 6,210,715 in view of Radin et al. In addition, the Examiners rejected Claims 1, 3, and 6-7 and 10 under the judicially created doctrine of obviousness-double patenting as being unpatentable over Claims 1, 8, 11, 20 and 31 of U.S. Patent No. 6,358,532 in view of Radin et al. Applicants hereby submit a terminal disclaimer to overcome these rejections based on double patenting.

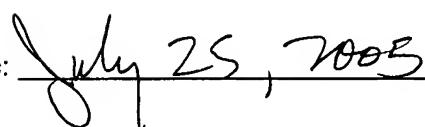
Based upon the foregoing, Applicants believe that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,

SHERIDAN ROSS P.C.

By: 

Gary J. Connell  
Registration No. 32,020  
1560 Broadway, Suite 1200  
Denver, Colorado 80202-5141  
(303) 863-9700

Date: 

J:\4141\2\pct\pus\Amendment and Response.wpd